

Claims:

What is claimed is:

1. A safety trocar assembly comprising:

- portal unit with elongated, tubular cannula having an open distal end;

5 - trocar unit having elongated obturator adapted to be removably inserted through said cannula and having a penetrating end exposed through said open distal end of said cannula and comprising a penetrating apex mechanical cutting means for making orifice in body cavity wall, and a sloping side wall;

10 - a protector means situated on said obturator and comprising penetrating apex shield adapted to actuate between a retracted and an extended position, when said shield surrounds said penetrating apex and said sloping side wall surrounds said shield from the outside;

- distal edge of said shield forms a hedge precluding the introduction and engagement of tissue fibers of body cavity wall both between said shield and said penetrating apex, and between said shield segments;

15 - bias means for biasing said shield toward said extended position and for permitting said shield move to said retracted position in response to a proximally directed force applied to said shield distal edge, said bias means, returning said shield to said extended position when the force applied to said shield distal edge is removed, which occurs when said penetrating apex and said shield distal edge have entered a patient's body cavity, however, before said
20 penetrating end has been fully inserted.

2. Device according to Claim 1, wherein said bias means has means made as spring mounted between said shield and parts of said trocar unit.

25 3. Device according to Claim 2, wherein said spring is situated in said obturator, preferentially in its distal part.

4. Device according to Claim 1, wherein said shield is tubular.

30 5. Device according to Claim 3, wherein said shield is made coiled springy rod.

6. Device according to Claim 5, wherein said shield is made integral with said spring.

7. Device according to Claim 1, wherein said penetrating apex is made as a separate
5 part mounted into said obturator.

8. Device according to Claim 1, wherein said penetrating apex is made integral with at
least distal part of said obturator.

9. Device according to Claim 1, which has longitudinal central axis and said obturator
10 and tubular cannula are situated coaxially with it.

10. Device according to Claim 9, wherein:

- the displacement vector of said protector means between its said extended and
15 retracted position is in the plane parallel to said longitudinal axis of trocar assembly;
- said cutting means comprises at least one cutting edge situated in the plane parallel to
said central longitudinal axis of the device so that this plane is the cutting plane of said cutting
edge;

- said protector means has a shield for protecting said cutting edge;

20 - said shield has shield outer surface and as such serves that section of said shield
surface which in the assembled position of said trocar assembly and when said shield is in said
extended position is located distally of said open distal end of tubular cannula and protrudes
beyond the bounds of members of said trocar assembly immovable relative to said tubular
cannula;

25 - said shield has shield height, and as such serves the distance between said cutting
plane and said shield outer surface;

- said shield has shield width, and as such serves the distance between said device
longitudinal axis and said shield outer surface;

30 - said shield has shield local comparative height, and as such serves the ratio of local
maximal height of said shield to local maximal width of said shield measured in their common

plane perpendicular to said device longitudinal axis;

- said shield has proximal protected position, and as such serves the extreme proximal position of said shield when there is the complete protection of said cutting edge;

- there is a screen area of said shield, and as such serves the section of said shield

5 which, when said shield is located in said proximal protected position, is situated between two planes perpendicular to said device longitudinal axis so that one of said planes intersects the proximal end of said cutting edge, whereas the other said plane intersects distal end of said cutting edge, and the plane equidistant from both said perpendicular planes divides said screen area into proximal and distal screen zone.

10 11. Device according to Claim 10, wherein said shield has shield zones located bilaterally of said cutting plane;

- there is full local comparative height of said shield, and as such serves the ratio of total local maximal height of said shield and said local maximal width, so that total local maximal height of said shield is the distance between outer surfaces of said shield zones measured along the line perpendicular to said cutting plane.

15 12. Device according to Claim 10, wherein there is a one- sided low profile shield situated laterally of said cutting plane, and said shield local comparative height along the proximal screen area is below 0.8.

20 13. Device according to Claim 11, wherein there is a two- sided low profile shield, and said shield full comparative height along the proximal screen area is below 1.4.

25 14. Device according to Claim 10, wherein said cutting means comprises penetrating apex cutting means situated inside of said penetrating apex shield.

30 15. Device according to Claim 14, wherein said penetrating apex cutting means are situated uniplanarly, whereas said penetrating apex has elongated transversal cross-section with largest axis lying uniplanarly with said penetrating apex cutting means.

16. Device according to Claim 10, wherein said cutting means has outer cutting means situated outside of said penetrating apex shield.

5 17. Device according to Claim 13, 16, wherein said penetrating apex cutting means and outer cutting means are made integral on the plate-shaped base, and said penetrating apex shield is made as two-sided low profile shield, and has longitudinal slot, said plate base passes through.

10 18. Device according to Claim 16, wherein there is at least one outer shield for said outer cutting means adapted to actuate between outer shield retracted - unprotected - position and outer shield extended - protected - position, and outer bias means for biasing said outer shield toward said extended position, permitting said shield move to said retracted position in response to a proximally directed force applied to body tissue operated surface of said outer
15 shield, said bias means returning said outer shield to said outer shield extended position when the force applied to said outer shield is removed so that said penetrating apex shield and outer shield are movable independently of one another and can be in at least three extreme mutual positions: their simultaneous location in said extended and outer shield extended position, respectively; location of said penetrating apex shield in said extended
20 position, and said outer shield in said outer shield retracted position; location of both in said retracted and outer shield retracted position, respectively.

19. Device according to Claim 18, wherein said outer cutting means have at least one outer cutting member made as a knife mounted on said penetrating end between said
25 penetrating apex shield and said outer shield so that the knife cutting edge protrudes above the surface of said sloping wall.

20. Device according to Claim 18, wherein there are two outer cutting members.

30 21. Device according to Claim 18, wherein there are three outer cutting members.

22. Device according to Claim 18, wherein said outer shield surrounds said penetrating apex, penetrating apex shield, and outer cutting means.

5 23. Device according to Claim 22, wherein said outer shield is made tubular, and said outer biasing means is made as a compression spring.

10 24. Device according to Claims 13, 19, wherein said outer shield is made as two-sided low profile shield, and comprises two rigidly interconnected plate-shaped shield members mounted bilaterally of said outer cutting means.

25. Device according to Claim 1, wherein:

15 - said portal unit has a portal housing located on the proximal end of said tubular cannula;

 - inner seals located in said portal housing and aimed to maintain insufflation of the body cavity;

 - locking means which being in lock position locks said protector means into protected position, and being in an unlock position unlocks said protector means so that said locking means unlocks said protector means when said cutting means is located distally of said seals.

20 26. Device according to Claim 25, wherein said locking means has obturator-situated controlling member, partially protruding laterally of said obturator and adapted for the interaction with inner surface of said tubular cannula for moving abutting member, which is spring-loaded to said obturator and has abutting surface for rigid abutment of said protector means members, when said locking means is in said lock position.

25 27. Device according to Claims 18, 26, wherein each of said independent shields has independent said locking means.

30 28. Device according to Claims 24, 27, wherein said penetrating apex shield and said

outer shield have independent said locking means.

29. Device according to Claim 18, 26, wherein there is said locking means for one of said shields, which in said protected position ensures protection of said penetrating apex and of all said cutting means.

30. Device according to Claims 23, 29, wherein there is said locking means to said outer shield.

31. Device according to Claim 16, wherein there are dilating means for dilating said orifice in body cavity wall, formed by said penetrating apex and cutting means to the dimensions permitting entry of said tubular cannula, therewith said dilating means comprises said sloping side wall and sloping edge of said open distal end of said tubular cannula so that said sloping edge of tubular cannula is located in the plane intersecting said device longitudinal central axis at an acute angle, whereas proximal end of said cutting edge of outer cutting means is situated proximally of distal point of said tubular cannula edge.

32. Device according to Claim 1, wherein there is portal unit mounting means for mounting said portal unit in said orifice of body cavity wall which has inner mounting means made as inflated cuff mounted on said tubular cannula, and there is connector means for said cuff connection to the external gas supply.

33. Device according to Claim 32, wherein there is an outer mounting means comprising restraining member movable along said tubular cannula, and resistance means precluding spontaneous proximal displacement of said restraining member.

34. Device according to Claim 33, wherein said restraining member has a flange and an orifice said tubular cannula passes through, and said resisting means is made as engagement means and has restraining member engagement protrusions situated on inner of said orifice, and tubular cannula engagement protrusions situated on outer surface of said tubular cannula.

35. Device according to Claim 32, wherein said connection means comprises connector with rebound valve and a passage connecting said connector and said cuff and passing through the wall of said tubular cannula.

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36. Device according to Claim 32, wherein there is outer sealing means to maintain insufflation of the body cavity precluding gas leakage out of body cavity into the atmosphere through the spacing between said portal unit and walls of said orifice in body cavity wall, and said outer sealing means has seal member, and said inflated cuff serves as such.

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37. Device according to Claim 36, wherein there is cuff traction means ensuring retaining of said inflated cuff against inner surface of body cavity wall in its inflated state.

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38. Device according to Claim 34, 35, 37, wherein said outer mounting means serve as said retaining means.

39. A safety trocar assembly comprising:

- portal unit having elongated obturator with penetrating distal end;
- longitudinal axis of trocar assembly;

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- penetrating means for orifice formation in body cavity wall, having at least two penetrating zones: first penetrating zone and second penetrating zone;

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- a protector means, having protector member for each of said penetrating zones and adapted to actuate between a retracted and an extended position, when each said protector member has body tissue operated surface which is the section of said protector member surface which contacts with body cavity wall tissue and while interacting with body tissue results in displacement of said protector member opposite of said extended position toward said retracted position so that displacement vectors of said protector members between their said retracted and extended positions are in the planes parallel to said longitudinal axis;

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- bias means for each of said protector members for biasing said protector members toward said extended position and for permitting said protector members move to said retracted

position in response to a force applied to said tissue operated surface, said bias means, returning said protector members to said extended position when the force applied to said tissue operated surface is removed so that said protector members move independently of one another between their said extended and retracted positions.

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40. Device according to Claim 39, wherein said penetrating means at the level of at least one said penetrating zone is made as cutting member with cutting edge so that said cutting edge is situated in the plane parallel to said longitudinal axis, and this plane is the cutting plane for said cutting edge.

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41. Device according to Claim 40, wherein said bias means is made as resilient members.

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42. Device according to Claim 41, wherein said protector members are made as separate shields.

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43. Device according to Claim 41, wherein said protector members are made as a common shield for at least two penetrating zones, a penetrating means made as said cutting members with common cutting edge so that each of said cutting members is protected by corresponding regions of said common shield so that each of said common shield regions is by its own said bias means.

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44. Device according to Claim 41, wherein there is at least one penetrating zone level limited by two planes perpendicular to said longitudinal axis, one of them intersecting the extreme distal point of said penetrating zone, whereas another one intersects the extreme proximal point of said penetrating zone.

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45. Device according to Claim 41, wherein there is a blunt penetrating apex, and said first and second penetrating zones are situated proximally of said blunt penetrating apex.

46. Device according to Claim 43, wherein said common shield and said bias means are made as a single resilient part having a slat which in said extended position is basically situated parallel to said cutting edge, and resilient elements, each of them being connected to said slat by one its end, whereas the other one is connected with the members of said penetrating end
5 immovable relative to said cutting edge.

47. Device according to Claim 43, wherein said common shield in said extended position extends beyond the bounds of said cutting edge no more than 2 mm in the direction parallel to said cutting plane of said cutting edge.

48. Device according to Claim 44, wherein there are at least two said penetrating zone levels, one being distal and another one, proximal.

49. Device according to Claim 44, wherein there are at least two said penetrating zones
15 in said penetrating zone level.

50. Device according to Claim 49, 42, 45, wherein there are two said cutting members, whereas said protector members are made as plates situated parallel to the corresponding said cutting members, and said bias means are made as compression springs and said blunt
20 penetrating apex is in line with said longitudinal axis.

51. Device according to Claim 48, wherein a section of said penetrating means at the level of said penetrating zone and corresponding to it said protector member and bias means are a penetration unit so that said distal and proximal penetration units are made so that the
25 penetration into body tissue at the level of said proximal penetration unit occurs under higher tissue tension than the penetration of tissue at the level of said distal penetration unit.

52. Device according to Claim 51, wherein rigidity of said proximal bias means of said proximal protector unit is higher than the rigidity of said distal bias means of said distal
30 protector unit.

53. Device according to Claims 46, 47, 48, wherein there is more than one said common shield, and they are situated around said longitudinal axis at regular intervals from each other.

5 54. Device according to Claims 52, 53, wherein said distal penetrating unit has said cutting member, said protector member is made plate-shaped and situated parallel to said cutting member, and said bias means is made as a flat compression spring.

10 55. Device according to Claim 39, wherein there is a portal unit with elongated tubular cannula, having an open distal end through which said penetrating end of said obturator is exposed.

56. Safety trocar assembly for making orifice in body cavity wall and for portal unit mounting in said orifice, comprising:

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- central longitudinal axis;
 - elongated obturator with distal penetrating end, having blunt apex and cutting means situated proximally of said blunt apex;

57. Device according to Claim 56, wherein said blunt apex has:

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- a base constituted by the section of said blunt apex situated at distal point level of said cutting means;
 - a blunt apex distal point formed by the extreme distal point on the surface of said blunt apex;
 - blunt apex central axis constituted by the axis parallel to said central longitudinal axis
 - 25 and intersecting said blunt apex distal point;
 - a diameter of said blunt apex base constituted by the diameter of a circumference made at the level of said base blunt apex and circumscribing the most protruding points on said surface of said base blunt apex so that the center of said circumference is located on said central axis blunt apex, and said circumference is in the plane perpendicular to said central axis
 - 30 blunt apex.

58. Device according to Claim 57, wherein said obturator has a diameter constituted by the diameter of the largest circumference with the centers on said central longitudinal axis made in the planes perpendicular to said central longitudinal axis, and circumscribing the most protruding points on the surface of said obturator at the distal half section of said obturator so that said diameter of base blunt apex constitutes less than 75% of said obturator diameter.

59. Device according to Claim 58, wherein said diameter of base blunt apex preferably constitutes less than 30% of said obturator diameter.

60. Device according to Claim 57, wherein end of said blunt apex is round.

61. Device according to Claim 60, wherein the diameter of said blunt apex end is less than said diameter of base blunt apex.

62. Device according to Claim 57, wherein said blunt apex central axis coincides with said central longitudinal axis.

63. Trocar assembly comprising:

- longitudinal central axis;
- portal unit with elongated tubular cannula, having an open distal end having at least one sloping edge situated in the plane intersecting said longitudinal central axis at an acute angle;
- trocar unit having elongated obturator adapted to be removably inserted through said cannula and having a cutting means for making orifice in body cavity wall, and exposed through said open distal end of said cannula;
- said cutting means has at least one cutting edge so that proximal end of said cutting edge is located proximally of distal point of said sloping edge of said tubular cannula.

64. Device according to Claim 57, wherein there is a cutting plane of said cutting edge

constituted by the plane intersecting said cutting edge and said longitudinal central axis;

65. Device according to Claim 64, wherein said cutting plane is the symmetry plane of said sloping edge.

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66. Device according to Claim 63, wherein there are more than one said cutting edge having differing said cutting planes.

67. Device according to Claim 66, wherein the number of said sloping edges corresponds to the number of said cutting planes.

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68. Trocar assembly comprising:

- portal unit with elongated tubular cannula and portal unit mounting means for mounting said portal unit in orifice of body cavity wall which has inner mounting means made as inflated cuff mounted on said tubular cannula, and there is connector means for said cuff connection to the external gas supply.

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69. Device according to Claim 68, wherein there is an outer mounting means comprising restraining member movable along said tubular cannula, and resistance means precluding spontaneous proximal displacement of said restraining member.

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70. Device according to Claim 69, wherein said restraining member has a flange and an orifice said tubular cannula passes through, and said resisting means is made as engagement means and has restraining member engagement protrusions situated on inner of said orifice, and tubular cannula engagement protrusions situated on outer surface of said tubular cannula.

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71. Device according to Claim 68, wherein said connection means comprises connector with rebound valve and a passage connecting said connector and said cuff and passing through the wall of said tubular cannula.

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72. Device according to Claim 68, wherein there is outer sealing means to maintain insufflation of the body cavity precluding gas leakage out of body cavity into the atmosphere through the spacing between said portal unit and walls of said orifice in body cavity wall, and said outer sealing means has seal member, and said inflated cuff serves as such.

73. Device according to Claim 72, wherein there is cuff traction means ensuring retaining of said inflated cuff against inner surface of body cavity wall in its inflated state.

74. Device according to Claim 70, 71, 73, wherein said outer mounting means serve as said cuff traction means.

75. A safety trocar assembly comprising:

- portal unit with elongated, tubular cannula having an open distal end;
- said portal unit has a portal housing located on the proximal end of said tubular cannula;
- trocar unit having elongated obturator adapted to be removably inserted through said cannula and having a penetrating end exposed through said open distal end of said cannula, and a cutting means for making orifice in body cavity wall, situated on said penetrating end;
- a protector means situated on said obturator and adapted to actuate between a retracted and an extended protected position;
- bias means for biasing said protector means toward said extended position and for permitting said protector means move to said retracted position in response to a proximally directed force applied to said protector means, returning said shield to said extended position when the force applied to said protector means is removed;
- inner seals located in said portal housing and aimed to maintain insufflation of the body cavity;
- locking means, which being in lock position, locks said protector means into protected position, and being in an unlock position unlocks said protector means so that said locking means unlocks said protector means when said cutting means is located distally of said seals.

76. Device according to Claim 75, wherein said locking means has obturator-situated controlling member, partially protruding laterally of said obturator and adapted for the interaction with inner surface of said tubular cannula for moving abutting member, which is spring-loaded to said obturator and has abutting surface for rigid abutment of said protector means members, when said locking means is in said lock position.

77. Device according to Claim 76, wherein said cutting means is made as knives, said protector means is made as a tubular member, and said bias means is made as a spring.

78. Safety trocar assembly comprising trocar unit having:

- elongated obturator;
- penetrating means situated on distal end of said obturator and having at least one penetrating zone;
- a protector means situated on said obturator and comprising shield for said penetrating zone and adapted to actuate between a retracted and an extended position;
- bias means for biasing said shield toward said extended position, and for permitting said shield move to said retracted position;
- longitudinal central axis of said obturator;
- displacement vector of said shield between their said extended and retracted positions is in the plane parallel to said longitudinal axis;
- said shield is made as one-sided low profile shield, and situated on one side of cutting plane of said penetrating zone, and along the proximal screen area has the shield local comparative height less than 0.8.

79. Device according to Claim 78, wherein there is a portal unit with elongated tubular cannula, having an open distal end through which said penetrating means and said shield are exposed so that said shield has shield open part and as such serves the section of said shield which by said shield location in said retracted position is situated between two planes perpendicular to said longitudinal central axis so that one of them intersects the distal point of

said shield, and the other said plane intersects the proximal point of the section of inner surface of said shield protruding beyond the bounds of the members of said trocar assembly immovable with regard to said penetrating means and located distally of said open distal end of tubular cannula.

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80. Device according to Claim 79, wherein said shield open part situated proximally of said screen area has the shield local comparative height less than 0.8.

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81. Device according to Claim 79, wherein inner diameter of said tubular cannula at the level of said open distal end is within 10 mm to 12.5 mm range so that said maximal height of said shield along the entire said shield open part is less than 3.5 mm.

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82. Device according to Claim 79, wherein inner diameter of said tubular cannula at the level of said open distal end is within 5 mm to 6.5 mm range so that said maximal height of said shield along the entire said shield open part is less than 2 mm.

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83. Device according to Claim 78, wherein said penetrating zone has cutting edge situated in the plane parallel to said longitudinal central axis, and said cutting edge has inner end point and outer end point so that said inner end point is situated closer to said longitudinal central axis than said outer end point.

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84. Device according to Claim 83, wherein said shield is direct shield, and by displacement from said extended position to said retracted one, it gradually exposes said cutting edge from said inner end point to said outer end point.

85. Device according to Claim 83, wherein said shield is delineating shield in which tissue operated edge is made approximately congruent to said cutting edge and exposes said cutting edge approximately concurrently along the entire length.

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86. Device according to Claim 83, wherein said shield is inverted shield and by its

displacement from said extended to said retracted position it gradually exposes said cutting edge from said outer end point to said inner end point.

87. Device according to Claim 83, wherein there is more than one said penetrating zone
5 and there is an inverted multishield, having protector members for each said penetrating zone so that said protector members are on a common base and upon displacement from extended to retracted position expose said penetrating zones from proximal to distal one.

88. Device according to Claim 80, 84, wherein said penetrating means is made as a
10 knife, where said cutting edge is made in the same plane with longitudinal central axis, said shield is made plate-shaped, and bias means is made as a flat compression means.

89. Device according to Claim 80, 86, wherein there is a blunt apex, two said cutting
15 edges situated on the common base set in a longitudinal groove of said distal end of said obturator so that said cutting edges are situated from two opposite sides of said obturator distal end at an acute angle to said longitudinal central axis, whereas said shield is made plate-shaped and has two said tissue operated edges, one for each said cutting edge so that said tissue
20 operated edges are made tilted with regard to said longitudinal axis so that their tilt angle is less than said tilt angle of cutting edges, and said bias means is made as a compression spring, and there is a lock means for blocking said shield in said extended position.

90. Device according to Claim 89, 80, wherein said cutting edge is situated at an acute
25 angle to said longitudinal central axis, and said tissue operated edge of said shield is made stepwise, and bias means is made as a compression spring,

91. A safety trocar assembly comprising:

- longitudinal central axis;
- portal unit with elongated, tubular cannula having an open distal end;
- trocar unit having elongated obturator adapted to be removably inserted through said
30 cannula and having a penetrating end exposed through said cannula open distal end;

- penetrating means situated on said penetrating end;
- a protector means for said penetrating means having at least one shield situated on said obturator and adapted to actuate between a retracted and an extended position when said shield protects said penetrating means;

5 - shield open part, this being the part of said shield which when said protector means is in said retracted position, is situated distally of the plane perpendicular to said longitudinal central axis and intersecting the proximal point of the section of outer surface of said shield protruding beyond the bounds of the members of said trocar assembly immovable with regard to said penetrating means and located distally of said cannula open distal end;

10 - common projection of outer surfaces of the members of said trocar assembly situated distally of said cannula open distal end onto the plane perpendicular to said longitudinal central axis, having the center in the intersect point of said plane and said longitudinal central axis;

- projection width of said shield and as such serves the distance between said common projection center and its most remote point on said shield projection outline;

15 - relative projection area of said shield outer outline which is the ratio of said projection area of shield outer outline to the area of the circle with radius equal to said projection width of said shield so that said relative projection area of said shield outer outline is always less than 0.4.

20 92. Device according to Claim 91, wherein said relative projection area of shield outer outline is less than 0.2.

93. A safety trocar assembly comprising:

25 - trocar unit with penetrating means having at least two penetrating zones - distal and proximal - so that penetration of body tissue at the level of said proximal penetration zone occurs under higher tissue tension than penetration of tissue at the level of said distal penetration zone.

30 - 94. Device according to Claim 93, wherein said penetrating means at the level

- of said distal and proximal zones are made as cutting members so that said distal

cutting member is made sharper than said proximal cutting member.

95. Device according to Claim 93, wherein there is a protector member for each of said penetrating zones so that the displacement of said proximal protector member from the extended to the retracted position demands greater effort than the displacement of said distal protector member.